



EESTI AKREDITEERIMISKESKUS
ESTONIAN ACCREDITATION CENTRE

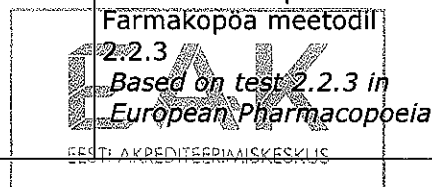
LISA Ravimiameti akrediteerimistunnistusele nr L217

ANNEX to the accreditation certificate No L217 of State Agency of Medicines

1. Akrediteerimisulatus on:

Accreditation scope is:

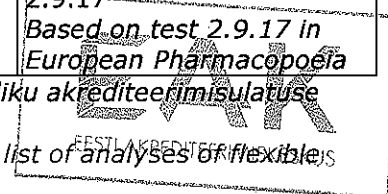
| Jrk nr No | Määratav näitaja Parameter | Katsetatav toode Products tested | Metoodika Procedure |
|--|---|---|--|
| Vedelikkromatograafia Liquid Chromatography | | | |
| 1. | Toimeaine, abiaine ja lisandite identifitseerimine ja sisaldus* <i>Assay, identification and impurity testing*</i> | Ravimite valmistamisel kasutatavad toorained, humaan- ja veterinaarravimid (tabletid, kapslid, vedelikud, salvid, pulbrid) <i>Human and veterinary medicinal products, active substances and excipients used in the manufacture of the medicinal products (Tablets, capsules, liquids, ointments, powders)</i> | LM-1/2015 Põhineb Euroopa Farmakopöa meetodil 2.2.29 <i>Based on method 2.2.29 in European Pharmacopoeia</i> |
| Tiitrimetria Titrimetric determination | | | |
| 2. | Toimeaine sisaldus * <i>Assay *</i> | Ravimite valmistamisel kasutatavad toorained, humaan- ja veterinaarravimid (tabletid, kapslid, vedelikud, salvid, pulbrid) <i>Human and veterinary medicinal products, active substances and excipients used in the manufacture of the medicinal products (Tablets, capsules, liquids, ointments, powders)</i> | LM-6/2018 Põhineb Euroopa Farmakopöa peatükil 4.2 <i>Based on chapter 4.2 in European Pharmacopoeia</i> |
| UV-Vis spektrofotomeetria UV-Vis Spectrophotometry | | | |
| 3. | Toimeaine või abiaine identifitseerimine, sisaldus ja lisandid * <i>Assay, identification and impurity testing *</i> | Ravimite valmistamisel kasutatavad toorained, humaan- ja veterinaarravimid (tabletid, kapslid, vedelikud, salvid, pulbrid) <i>Human and veterinary medicinal products, active substances and excipients used in the manufacture of the medicinal products (Tablets, capsules, solutions, ointments, powders)</i> | LM-4/2017 Põhineb Euroopa Farmakopöa meetodil 2.2.25 <i>Based on test 2.2.25 in European Pharmacopoeia</i> |
| Elektrokeemilised määramised Electrochemical determinations | | | |
| 4. | pH <i>pH</i> | Vedelikud <i>Liquids</i> | LM-12/2013 Põhineb Euroopa Farmakopöa meetodil 2.2.3 <i>Based on test 2.2.3 in European Pharmacopoeia</i> |



| Jrk nr No | Määratav näitaja Parameter | Katsetatav toode Products tested | Metoodika Procedure |
|---|--|---|--|
| Gravimeetria Gravimetric determination | | | |
| 5. | Kuivatuskadu <i>Loss on drying</i> | Ravimite valmistamisel kasutatavad toorained, humaan- ja veterinaarravimid (tabletid, kapslid, pulbrid), droogid. <i>Human and veterinary medicinal products, active substances and excipients used in the manufacture of the medicinal products (tablets, capsules, powders), herbals</i> | LM-11/2019 Põhineb Euroopa Farmakopöa meetodil 2.2.32 <i>Based on test 2.2.32 in European Pharmacopoeia</i> |
| 6. | Keskmine mass ja massihälve <i>Average mass and uniformity of mass</i> | Tabletid, kapslid, pulbrid, suposiidid <i>Tablets, capsules, powders, suppositories</i> | LM-18/2017 Põhineb Euroopa Farmakopöa meetodil 2.9.5 ja 2.9.27 <i>Based on test 2.9.5 and 2.9.27 in European Pharmacopoeia</i> |
| Muud meetodid Other methods | | | |
| 7. | Vedelike tihedus <i>Density of solution</i> | Vedelikud <i>Liquids</i> | LM-24/2017 Põhineb Euroopa Farmakopöa meetodil 2.2.5. <i>Based on test 2.2.5 in European Pharmacopoeia</i> |
| 8. | Silmale nähtamatud osakesed <i>Sub-visible particles</i> | Süste – ja infusioonilahused, pulbrid süste – ja infusioonilahuste valmistamiseks <i>Solutions for injection and infusion, powder of solution for injection and infusion</i> | LM-15/2016 Põhineb Euroopa Farmakopöa meetodil 2.9.19 <i>Based on method 2.9.19 in European Pharmacopoeia</i> |
| 9. | Toimeaine vabanemine <i>Dissolution Test</i> | Tabletid, kapslid <i>Tablets, capsules</i> | LM-19/2015 Põhineb Euroopa Farmakopöa meetodil 2.9.3 <i>Based on method 2.9.3 in European Pharmacopoeia</i> |
| 10. | Tablettide ja kapslite lagunemisaeg <i>Disintegration of tablets and capsules</i> | Tabletid, kapslid <i>Tablets, capsules</i> | LM-22/2016 Põhineb Euroopa Farmakopöa meetodil 2.9.1 <i>Based on test 2.9.1 in European Pharmacopoeia</i> |
| 11. | Lahuse maht <i>Volume of Solution</i> | Vedelikud <i>Liquids</i> | LM-23/2015 Põhineb Euroopa Farmakopöa meetodil 2.9.17 <i>Based on test 2.9.17 in European Pharmacopoeia</i> |

* Paindlik akrediteerimisulatus on kirjeldatud labori dokumendis „Paindliku akrediteerimisulatus analüütide loetelu“

* Description of flexible scope is described in laboratory document "The list of analyses of flexible accreditation scope"



2. Katsetamist/mõõtmist teostav struktuuriüksus: Ravimiameti labor

Part of legal entity that provides testing/measurement: Quality Control Laboratory of State Agency of Medicines

Tegevuskohtade aadressid: Nooruse 1, Tartu 50411


Addresses of locations:

3. Labor on akrediteeritud standardi EVS-EN ISO/IEC 17025:2017 nõuete suhtes

Laboratory is accredited against the requirements of standard EVS-EN ISO/IEC 17025:2017



Kristiina Saarniit
EAK juhataja
Director of EAK



Maia Valm
Peaassessor
Lead Assessor

Tallinn, 25.06.2019